

16th February 2018 Information Technology EMA/396650/2016

eAF DES Change Summary

Summary of DES changes applied to v.1.22.0.1

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Purpose

The aim of this document is to summarise the changes applied to the Data Exchange Standard covering all forms for version 1.22.0.1 of the Electronic Application Form.

It should be noted this document in no way replaces the current DES documents for each of the forms.

In all instances, and to facilitate understanding, an extract of the original schema definition is supplied, along with the updated version.

The document has one section which explains about one schema defect in below forms:

- MAA Human
- MAA Vet
- Renewal

To enabled cross reference to the release notes for 1.22.0.1, this document will reference the corresponding defect reference number associated with the DES change.

Defects

1. EAF-2810

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Summary of defect (EAF-2810):

org-modifiedDate node is removed in the common Dictionary schema. The sections affected in the pdf forms are listed below.

Human Form / Veterinary form

Section 2.5.1.a Admin & Manufacturer Section 2.5.2 Admin & Manufacturer Section 2.5.3 Admin & Manufacturer

Renewal Form

- Section 2 Batch Control Testing Admin & Manufacturer Section 2 Medicinal Product Admin & Manufacturer
- Section 2 Active Substance Section 2 Batch Release
- Section 2 Batch Release Admin & Manufacturer
- Section 2 For blood Products Admin & Manufacturer

Original eaf_Dictionary xsd Schema definition:

~~>	
	complexType name="admin-office">
	<pre><xs:sequence> </xs:sequence></pre>
	<pre><xs:element name="company-name" type="rdm:string100"></xs:element> </pre>
	<xs:element name="address1" type="rdm:string100"></xs:element>
	<xs:element name="address2" type="rdm:string100"></xs:element>
	<xs:element name="address3" type="rdm:string100"></xs:element>
	<xs:element name="address4" type="rdm:string100"></xs:element>
	<xs:element name="poBox" type="rdm:string100"></xs:element>
	<xs:element name="city" type="rdm:string100"></xs:element>
	<xs:element minoccurs="0" name="state" type="rdm:string100"></xs:element>
	<xs:element name="county" type="rdm:string100"></xs:element>
	<xs:element name="post-code" type="rdm:string10"></xs:element>
	<xs:element name="country" type="rdm:control-term"></xs:element>
	<xs:element name="orgID" type="rdm:string30"></xs:element>
	<xs:element name="locID" type="rdm:string30"></xs:element>
	<xs:element name="org-modifiedDate" type="xs:date"></xs:element>
	<xs:element name="log-modifiedDate" type="xs:date"></xs:element>
	<xs:element name="phone" type="rdm:string50"></xs:element>
	<xs:element name="fax" type="rdm:string30"></xs:element>
	<xs:element name="email" type="rdm:string100"></xs:element>
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<**	<pre><xs:sequence> <xs:element name="company-name" type="rdm:string100"></xs:element> <xs:element name="address1" type="rdm:string100"></xs:element> <xs:element name="address2" type="rdm:string100"></xs:element> <xs:element name="address3" type="rdm:string100"></xs:element></xs:sequence></pre>
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<**	<pre><xs:sequence> <xs:element name="company-name" type="rdm:string100"></xs:element> <xs:element name="address1" type="rdm:string100"></xs:element> <xs:element name="address2" type="rdm:string100"></xs:element> <xs:element name="address3" type="rdm:string100"></xs:element> <xs:element name="address4" type="rdm:string100"></xs:element> <xs:element name="poBox" type="rdm:string100"></xs:element> <xs:element company-name"="" name="poBox" type="rdm:string100"></xs:element> <xs:element name="address1" type="rdm:string100"></xs:element> <xs:element name="address2" type="rdm:string100"></xs:element> <xs:element name="address3" type="rdm:string100"></xs:element> <xs:element name="address4" type="rdm:string100"></xs:element> <xs:element name="poBox" type="rdm:string100"></xs:element> <xs:element name="city" type="rdm:string100"></xs:element> </xs:sequence></pre>
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< x 3	<pre><xs:sequence></xs:sequence></pre>

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Updated/Amended eaf_Dictionary xsd schema definition:

```
<xs:complexType name="admin-office">
    <xs:sequence>
        <xs:element name="company-name" type="rdm:string100"/>
        <xs:element name="address1" type="rdm:string100"/>
        <xs:element name="address2" type="rdm:string100"/>
        <xs:element name="address3" type="rdm:string100"/>
        <xs:element name="address4" type="rdm:string100"/>
        <xs:element name="poBox" type="rdm:string100"/>
        <xs:element name="city" type="rdm:string100"/>
        <xs:element name="state" type="rdm:string100" minOccurs="0"/>
        <xs:element name="county" type="rdm:string100"/>
        <xs:element name="post-code" type="rdm:string10"/>
        <xs:element name="country" type="rdm:control-term"/>
        <xs:element name="orgID" type="rdm:string30"/>
        <xs:element name="locID" type="rdm:string30"/>
        <xs:element name="loc-modifiedDate" type="xs:date"/>
        <xs:element name="language" type="rdm:string30"/>
        <xs:element name="phone" type="rdm:string50"/>
        <xs:element name="fax" type="rdm:string30"/>
        <xs:element name="email" type="rdm:string100"/>
    </xs:sequence>
</xs:complexType>
<xs:complexType name="manu-facility">
    <xs:sequence>
        <xs:element name="company-name" type="rdm:string100"/>
        <xs:element name="address1" type="rdm:string100"/>
        <xs:element name="address2" type="rdm:string100"/>
        <xs:element name="address3" type="rdm:string100"/>
        <xs:element name="address4" type="rdm:string100"/>
        <xs:element name="poBox" type="rdm:string100"/>
        <xs:element name="city" type="rdm:string100"/>
        <xs:element name="state" type="rdm:string100" minOccurs="0"/>
        <xs:element name="county" type="rdm:string100"/>
        <xs:element name="post-code" type="rdm:string10"/>
        <xs:element name="country" type="rdm:control-term"/>
        <xs:element name="orgID" type="rdm:string30"/>
        <xs:element name="locID" type="rdm:string30"/>
        <xs:element name="loc-modifiedDate" type="xs:date"/>
        <xs:element name="language" type="rdm:string30"/>
        <xs:element name="phone" type="rdm:string50"/>
        <xs:element name="fax" type="rdm:string30"/>
        <xs:element name="email" type="rdm:string100"/>
    </xs:sequence>
</xs:complexType>
```

The org-modifiedDate node is removed : <xs:element name="org-modifiedDate" type="xs:date"/>

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